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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,132	05/29/2001	Knut E. Rasmussen	01-11 US	9635

7590

09/24/2003

Varian Inc
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EXAMINER

PADMANABHAN, KARTIC

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 09/24/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,132

Applicant(s)

RASMUSSEN ET AL.

Examiner

Kartic Padmanabhan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/28/03 has been entered.

Election/Restrictions

2. Applicant's election with traverse of Group II in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the groups are not independent because they share the same technical features. This is found persuasive, and the restriction requirement is herein withdrawn.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 21-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 21, 31, 42, 48, and 54 are rejected as vague and indefinite for the recitation of "a second hollow container" because it is unclear, with this terminology, if the first container must be hollow as well. Applicant should use the following wording to clarify the claims: "a second container that is hollow disposed..."

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6. Claim 36 is rejected as vague and indefinite because it does not end in a period, and it appears that part of the claim has been omitted.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 21-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasmussen et al. (WO 97/25606) in view of Berg (US Pat. 6,164,144).

Rasmussen et al. teach a device and method for liquid-liquid microextraction. The method comprises providing a carrier, modifying the carrier, immobilizing a solvent (acceptor solution) on the carrier surface, contacting the carrier with the sample (which may be in solution), concentrating and fixing the analyte of interest to the solvent, and analyzing the carrier. Preferably, a fiber is used as the carrier. The fibers for use with the invention may be made of porous polymers such as polyacrylate. The amount of solvent to be immobilized on the solvent is in the range of 1-5 ul (page 4). The carrier with immobilized solvent is inserted into the sample solution, where the pH may be altered to favor partitioning of analyte and solvent (page 5). The solvent of the reference is preferably a high boiling solvent, such as octanol (page 5). In one embodiment, the fiber is withdrawn into the needle of a syringe, and the needle is used to penetrate the septum of a solvent vial, at which time the fiber is lowered and solvent is immobilized. The fiber is then withdrawn back into the needle and used to penetrate the sample vial. After the fiber is lowered into the vial, analytes are partitioned by agitating the vial (page 7). Since the fiber only accommodates 1-5 ul of sample, it is inherent that the sample vial has a volume greater than 50X this amount. The sample solution for use with the invention may be plasma. However, the reference does not specifically teach the use of a hollow fiber or an acidified acceptor solution.

Berg teaches methods and device for solid phase microextraction (SPME). The reference teaches the use of a hollow fiber with SPME, wherein the fiber acts as a "sponge". In addition, the reference also teaches the use of a magnetic stirring bar as the means of agitation of a sample in a vial.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use a magnetic stirring bar, a hollow fiber, and an acidified acceptor solution with the invention of Rasmussen et al. By using a hollow fiber, one would have been able to fill the fiber with acceptor solution rather than immobilizing the solution on the surface of the fiber. With such an arrangement, partitioning will occur between analyte and acceptor within the porous fiber, at which time acceptor solution with analyte can be removed and analyzed. Alternatively, if desired, one could have also allowed analyte to permeate through the other side of the fiber before collection for analysis. One would have been able to use this arrangement with a reasonable expectation that it would provide results similar to those when acceptor is immobilized on the surface of the fiber. Depending on the analyte of interest, one of ordinary skill in the art would have had a reasonable expectation of success in selecting hollow fibers with pores of the required size such that analyte would be permeable to the desired analyte. It would have further been obvious to use a magnetic bar as the stirring means to establish extraction equilibrium (partitioning between sample and acceptor) for the analyte because magnetic stirring bars are very well known in the art for use when agitation is necessary, as taught by Berg et al. One would have had a reasonable expectation of success in using a stirring bar as the agitation means with the method of Rasmussen et al. because both Berg and Rasmussen et al. are drawn to extraction methods and one would have recognized that any agitation means could have been used with the method and device of Rasmussen et al. Furthermore, it would have been obvious to acidify the acceptor solution of Rasmussen et al. because Diazepam, the analyte of interest in Example 1, has its highest partition coefficient at an acidic pH. Finally, it would have also been obvious to modify the method and device of Rasmussen et al. by using a sponge instead of a

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fiber as the disposable container. Since Berg teaches that the fiber of the method acts as a sponge, one would have had a reasonable expectation of success in carrying out the method of Rasmussen et al. with the replacement of the fiber with a sponge material. In addition, although Berg deals with solid phase microextraction, the teaching of Berg would have been applicable to the modified method of Rasmussen et al. because Rasmussen et al. use a SPME fiber in their liquid-liquid microextraction method (page 10).

Response to Arguments

11. Applicant's arguments filed March 28, 2003 have been fully considered, but they are not persuasive.

12. In response to applicant's arguments that neither Rasmussen nor Berg teach LLME or LLLME where analyte passes through the membrane wall and is collected on the opposite side, the examiner agrees. However, the examiner maintains that such an arrangement would have been obvious to one of ordinary skill in the art at the time of the invention. Applicant is directed to the 35 USC 103 rejection above. It is also noted that the claims merely recite the use of fibers permeable to the analyte; however, there is no positive recitation in the claims that the analyte actually permeate through the fibers. Therefore, the claims do not require the analyte to actually permeate through the hollow fibers, even though the fiber is permeable to analyte, but merely requires hollow fibers that allow this step to occur.

Conclusion

Claims 21-58 are rejected.

References: Both Cussler references are cited as art of interest for teaching methods and devices for liquid extractions.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641



LONG V. LE
SUPERVISORY PATENT EXAMINER
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09/22/03